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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,026	10/21/2005	Hideaki Shimada	Q90951	1874
23373 7590 09/25/2007 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER CARLSON, KAREN C	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 09/25/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/554,026

Applicant(s)

SHIMADA ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 6 and 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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This Office Action is in response to the paper filed August 1, 2007.

Claims 1-14 are currently pending. The Examiner has withdrawn Claims 3, 4, 6, and 8-14 from further consideration because these claims are drawn to non-elected inventions. Claims 1, 2, 5, and 7 are currently under examination, elected without traverse in the reply filed on March 26, 2007.

Benefit of priority is set to April 21, 2003.

Withdrawal of Rejections:

The rejection of Claims 1, 2, 5, and 7 under 35 U.S.C. 101, is withdrawn.

The rejection of Claims 1, 2, 5, and 7 are rejected under 35 U.S.C. 112, second paragraph, is withdrawn.

Maintenance of Rejections, modified in response to amendments:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Note that Liu et al.'s FIR is cited at pages 4, line 22 of the specification, and at page 10 last paragraph through page 11 FIR is cited with other proteins known to interact with FUSE binding protein.

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Claims 1, 2, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. (2000; The FBP interacting repressor targets TFIIH to inhibit activated transcription. *Molecular Cell* 5: 331-341).

Liu et al. teach FUSE binding protein interacting repressor (FIR) consisting of SEQ ID NO: 2 – see the amino acid sequence at Fig. 2A and the sequence alignment attached to this Office Action. Liu et al. also made derivatives of FIR. For example, Liu et al. made deletion derivatives consisting of amino acids 145-542 and 1-377 of FIR (page 339, left col., line 26) and addition derivatives of SEQ ID NO: 2 with GST or His tag (page 339, left col., line 24), or a combination of the two – GAL4 chimeras comprising amino acids 1-121, 55-542, or 121-542 of FIR (page 339, left col., lines 28-29) and GST chimeras comprising amino acids 1-113 (page 339, right col., "Helicase Assay"). Chimeras comprising N-terminally truncated FIR are also considered to be substitution derivatives of FIR. *At page 339, left col., para. 4, wherein Liu et al. teach that the proteins were placed in sodium phosphate (buffer), NaCl, Triton X, PMSF, DTT and in the right col, top as drawn to elution of FIR into sodium phosphate buffer, NaCl, and imidazole and at para. 2, placed in BC-100 buffer, HEPES, NaCl, Triton X.*

Therefore, Liu et al. teach a composition of FIR, an agent that interacts with FUSE binding protein with at least one pharmaceutical agent as set forth in claim 1 (**Claim 1**). FIR consists of SEQ ID NO: 2 and Liu et al. made derivatives of SEQ ID NO: 2 comprising amino acid deletions, substitutions, and additions, and partial fragments thereof (**Claim 2**). At page 15, paras. 2 and 3 of the specification, the specification states that a protein can be prepared to have a form that can be introduced into cells without changing structure and function of the protein and such introduction can be made by a micro-injection method. Thus, the purified form of FIR is in a form for introduction into cells via microinjection, for example (**Claims 5**). **Claim 7** is included in this rejection because the intended use of the product does not provide a patentable limitation to the product as claimed.

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The demonstration of a new activity for a known protein is considered to be further characterization of the known protein and is not evidence of novelty for the protein.

Applicants urge that Claim 1 is drawn to a pharmaceutical composition and that Liu et al. do not disclosed the composition of Claim 1. The Examiner notes that the composition of Claim 1 comprises FIR and a buffer, for example, that need not be suitable/sterile for injection into a subject. None-the-less, the elution of FIR into sodium phosphate buffer, NaCl, and imidazole as set forth on page 339, top right col. would meet this limitation if presented.

New Objection:

Claim 5 is objected to because of the following informalities: Claim 5 depends from withdrawn claims. Appropriate correction is required.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink that reads "Karen Cochrane Carlson" followed by a stylized "Ph.D." in parentheses.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER